



JAN 13 2006

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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,886,036

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,886,036, which claims the human drug product Kaletra® (a combination of lopinavir and ritonavir), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 325 days (0.9 years).

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 325 days (0.9 years).

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 21, 2001 (66 Fed. Reg. 48687). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,290 - 854) + 107 \\ &= 325 \text{ days (0.9 years)}\end{aligned}$$

Since the regulatory review period began November 20, 1996, before the patent issued (March 23, 1999), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From November 20, 1996 to, and including, March 23, 1999 is 854 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,886,036
Granted:	March 23, 1999
Original Expiration Date <sup>1</sup> :	December 29, 2012
Applicant:	Kempf et al.

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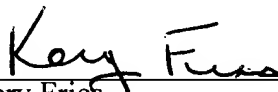
<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record: Abbott Laboratories  
Title: RETROVIRAL PROTEASE INHIBITING  
COMPOUNDS  
Product Trade Name: Kaletra® (lopinavir/ritonavir)  
Term Extended: 325 (0.9 years)  
Expiration Date of Extension: November 19, 2013

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Patent Ext. By FAX: (571) 273-7755  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.

  
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Kery Fries  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane  
Rockville, MD 20857

RE: Kaletra® (lopinavir/ritonavir)  
FDA Docket No.: 01E-0089

Attention: Claudia Grillo